Clark & Elbing LLP

101 Federal Street
Boston, MA 02110

Telephone 617-428-0200
Facsimile 617-428-7045
617-428-7046

Date: August 18, 2003

To: Examiner Dixon
Petitions Office
T.C. 1600

Facsimile No: (703) 872-9307

From: Kristina Bieker-Brady, Ph.D.

Re: POLYCLONAL ANTIBODY COMPOSITION FOR TREATING ALLERGY
U.S.S.N. 09/866,573
Our Reference No. 50190/005001

Pages: 17, including this transmittal page.

Message: Petition to Withdraw Finality

PROSECUTION

PATENT
ATTORNEY DOCKET NUMBER: 50190/005001

The U.S. PTO date stamp sets forth the date of receipt of:

Applicant/Patentee: HAURUM ET AL

Serial/Patent Number: 09/866,573

Filed/Issued: MAY 25, 2001

Title: POLYCLONAL ANTIBODY COMPOSITIONS FOR TREATING...

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☐ Notice to File Missing Parts	Pages:	☐ Assignment & Cover Sheet	Pages:
☐ Reply to Missing Parts	Pages:	☐ Change of Address	Pages:
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PROSECUTION

PATENT
ATTORNEY DOCKET NUMBER: 50190/005001

The U.S. PTO date stamp sets forth the date of receipt of:

Applicant/Patentee: John S. Haurum et al.

Serial/Patent Number: 09/866,573

Filed/Issued: May 25, 2001

Title: Polyclonal Antibody Composition for Treating...

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	John S. Haurum et al.	Art Unit:	1644
Serial No.:	09/866,573	Examiner:	Patricia Nolan
Filed:	May 25, 2001	Customer No.:	21559

Title: POLYCLONAL ANTIBODY COMPOSITION FOR TREATING ALLERGY

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PETITION FOR WITHDRAWAL OF FINALITY UNDER 37 C.F.R. § 1.181

This is a Petition for Withdrawal of Finality of the Office Action mailed January 28, 2003.

Applicants respectfully request expeditious consideration of this Petition in view of the posture of this case. A Notice of Appeal was filed in this case on July 24, 2003.

THE CLAIMS

1. (Not entered) A pharmaceutical composition comprising as an active ingredient a recombinant polyclonal antibody capable of reacting with or binding to proteins or epitopes derived from an inhaled, ingested, or airborne allergen, together with one or more pharmaceutically acceptable excipients, wherein said pharmaceutical composition is free of the allergen to which said recombinant polyclonal antibody is reactive or binds.

Claims 2-4: Cancelled.

5. (Previously presented) A pharmaceutical composition according to claim 1, which composition is free of the allergen to which the antibody is reactive or binds.

6. (Previously presented) A pharmaceutical composition according to claim 1, comprising at least one pharmaceutically acceptable excipient capable of effecting topical application of said recombinant polyclonal antibody.

7. (Previously presented) A pharmaceutical composition according to claim 5, which is intended for topical administration to the oropharynx, nasal cavity, respiratory tract, gastrointestinal tract, conjunctival mucosa, vagina, urogenital mucosa, or for dermal application.

8. (Previously presented) A pharmaceutical composition according to claim 7, wherein the respiratory tract is selected from nasal, oral, pharyngeal, bronchial, or alveolar mucosa.

9. (Previously presented) A pharmaceutical composition according to claim 1, which is provided as a solution, dispersion, powder or in the form of microspheres.

10. (Previously presented) A pharmaceutical composition according to claim 1, wherein the recombinant polyclonal antibody is generated by phage display technology.

11. (Original) A pharmaceutical composition according to claim 10, wherein the recombinant polyclonal antibody is generated under such conditions that the immunoglobulin heavy chain variable region and light chain variable region gene segments are linked together in a parental library in order to allow for the bulk transfer of variable region light chain and heavy chain gene pairs from one vector to another, while allowing stable pairing of specific immunoglobulin variable region light chain and heavy chain gene segments as they are present upon selection from the parental library of immunoglobulin variable region light chain and heavy chain gene segment pairs encoding antibody molecules capable of reacting with or binding to an allergen.

12. (Original) A pharmaceutical composition according to claim 10, wherein the recombinant polyclonal antibody is generated under such conditions that the immunoglobulin heavy chain variable region and light chain variable region gene segments are linked together in order to allow for the bulk transfer of specific variable region light chain and heavy chain gene pairs from one vector to another, while allowing stable pairing of specific immunoglobulin variable region light chain and heavy chain gene segments as they are present in the original polyclonal immune response of an animal or human individual.

13. (Previously presented) A pharmaceutical composition according to claim 1, wherein the allergen is an allergen of house dust mites, dander from cat, dander from dog, dander from horse, tree pollen, grass pollen, or fungi.

14. (Previously presented) A pharmaceutical composition according to claim 1, comprising the recombinant polyclonal antibody in an amount in the range of 1µg to 1g

per unit dosage form.

Claims 15-34: Canceled.

35. (Previously presented) A pharmaceutical composition according to claim 1, wherein said polyclonal antibody is an IgG antibody.

36. (Withdrawn) A pharmaceutical composition according to claim 1, wherein said polyclonal antibody is an IgM antibody.

37. (Withdrawn) A pharmaceutical composition according to claim 1, wherein said polyclonal antibody is an IgA antibody.

38. (Withdrawn) A pharmaceutical composition according to claim 1, wherein said polyclonal antibody is an IgD antibody.

39. (Previously presented) A pharmaceutical composition according to claim 1, wherein said polyclonal antibody has antibody molecules from a mixture of antibody classes.

40. (Previously presented) A pharmaceutical composition according to claim 1, wherein said polyclonal antibody binds said allergen with sufficient density to mediate the elimination of said allergen from a patient.

41. (Previously presented) A pharmaceutical composition according to claim 1, wherein said polyclonal antibody binds said allergen with a higher antibody density than a monoclonal antibody.

42. (Previously presented) A pharmaceutical composition according to claim 1, wherein said polyclonal antibody does not cross-react with endogenous self-antigens in a patient.

43. (Previously presented) A pharmaceutical composition according to claim 1, wherein said polyclonal antibody does not elicit an anaphylactic response in humans.

44. (Previously presented) A pharmaceutical composition according to claim 1, wherein said polyclonal antibody is a fully human antibody.

45. (Previously presented) A pharmaceutical composition according to claim 1, wherein the variable region of said polyclonal antibody has a mutation.

46. (Previously presented) A pharmaceutical composition according to claim 1, wherein at least 85% of the antibody molecules in said composition are target-specific.

47. (Previously presented) A pharmaceutical composition according to claim 1, wherein at least 90% of the antibody molecules in said composition are target-specific.

48. (Previously presented) A pharmaceutical composition according to claim 1, wherein said polyclonal antibody is a complete antibody molecule or fragment thereof such as an F_{ab} fragment.

49. (Previously presented) A pharmaceutical composition according to any of claim 1, wherein said composition is provided as a microsphere, liposome, polyethylene glycol-conjugated complex, or complex of positively or negatively charged excipients with antibody molecules of the opposite charge, wherein said composition prolongs the clearance of said polyclonal antibody in a patient.

REMARKS

Applicants respectfully submit that the final rejection asserted by the Examiner in the Office Action mailed January 28, 2003 was premature and finality should be withdrawn. Further, Applicants request that the claim amendments submitted in Applicants' Reply of April 28, 2003 be entered and the arguments considered.

Status of Amendments

The claim amendments submitted in Applicants' Reply of April 28, 2003 have not been entered.

Applicants note that claim 7 was inadvertently unamended in Applicants' Reply and remained dependent from claim 5, a claim proposed to be canceled. The Examiner pointed out this oversight in the Advisory Action mailed July 7, 2003. In a subsequent telephonic interview with the attorney of record, the Examiner refused to enter an amendment correcting the dependency of claim 7. Because of this improper dependency, the Examiner asserted that the other amendments contained in Applicants' Reply were not entered, nor were Applicants' remarks in the Reply considered. A Supplemental Amendment correcting the dependency of claim 7 will be promptly filed should the amendments in Applicants' Reply of April 28, 2003, be entered.

Claims Under Examination in the Final Office Action Mailed January 28, 2003

Claim 1, the sole independent claim under examination, was amended in Applicants' Reply mailed June 6, 2002. The amendment was entered and examined, resulting in the Final Office Action mailed January 28, 2003. Claim 1 was amended in Applicants' Reply of June 6, 2003, as follows:

> 1. A pharmaceutical composition comprising as an active ingredient a recombinant polyclonal antibody capable of reacting with or binding to proteins or epitopes derived from an inhaled, ingested, or airborne [[an]] allergen, together with one or more ~~pharmaceutical~~ pharmaceutically acceptable excipients.

Legal Standard for Final Rejections

Applicants respectfully submit that the rejection set forth in the Final Office Action mailed January 28, 2003 was prematurely made final. The M.P.E.P. § 706.07(a) sets forth the analytical framework for properly entering a final rejection. This section states (emphasis added):

> Under present practice, second or any subsequent action on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).
>
> *****
>
> A second or any subsequent action on the merits in any application ... should not be made final if it includes a rejection, on prior art not of record, of any claim amended to include limitations which should reasonably have been expected to be claimed. . . . . .

Thus, the M.P.E.P. § 706.07(a) provides circumstances in which a second or subsequent action should not be made final. Applicants submit that the facts of the present case satisfy both of the above-identified exceptions and that satisfying either of the exceptions is sufficient to properly withdraw the finality of the Office Action mailed January 28, 2003.

The New Ground of Rejection Not Necessitated by Applicants' Amendment

The Examiner asserts, in the Final Office Action mailed January 28, 2003, that the new ground of rejection was necessitated by the amendment filed in Applicants' Reply mailed June 6, 2002. All pending claims were thus finally rejected, under 35 U.S.C. § 103(a), over U.S. Patent No. 4,740,371 (newly cited; "the '371 patent"), in view of U.S. Patent No. 5,789,208 (art of record; "the '208 patent").

Applicants respectfully submit that the newly asserted obviousness rejection was

not necessitated by Applicants' amendment for two distinct reasons. First, the amendment served to narrow the scope of the claimed invention. Prior to the amendment, the claimed pharmaceutical composition contained "as an active ingredient a recombinant polyclonal antibody capable of reacting with or binding to [any] allergen." The amendment reduced the recombinant polyclonal antibodies to those that are capable reacting with or binding to "proteins or epitopes derived from inhaled, ingested, or airborne allergen." Thus, any rejection for obviousness that may be asserted against the more narrow claim could properly have been asserted against the broader claim.

Second, the newly cited art is not relevant to the subject matter of the amendment. The Examiner characterizes the newly cited '371 patent as teaching

> pharmaceutical compositions of IgG polyclonal antibody or mixtures of antibody classes for the treatment of allergies wherein said polyclonal antibodies are human, complexed with negatively or positively charged excipients, are 100% target specific, do not elicit an anaphylactic response in humans, do not cross react with self antigens in a patient are given in a concentration with sufficient density to mediate the elimination of an allergen from a patient, are formulated for topical nasal administration, are free of the allergen to which the antibody is reactive (see specifically column 8, lines 15-33, in particular), are provided as a solution and wherein the allergen is derived from house dust mites in the range of 1μg to 1g per unit dosage form. *Final Office Action* mailed January 28, 2003, paragraph bridging pages 2-3.

In making the obviousness rejection based on the '371 patent, the Examiner states that

> [o]ne of ordinary skill in the art ... would have been motivated to substitute recombinant polyclonal antibodies taught by the '208 patent for conventional polyclonal antibodies as taught by the '371 patent for treating allergies. *Final Office Action* mailed January 28, 2003, page 3, second paragraph.

Nothing in the Examiner's treatment of the '371 patent addresses Applicants' amendment regarding "proteins or epitopes derived from inhaled, ingested, or airborne allergen." Accordingly, the Examiner's characterization of the '371 patent and the newly asserted rejection does not distinguish between the antibodies encompasses by the unamended claims compared to the claims as amended in Applicants' Reply mailed June 6, 2002.

The '371 patent and the rejection therefore could have properly been asserted in the previous, non-final Office Action but was not.

Because this new rejection was neither asserted in the previous Office Action nor necessitated by Applicants amendment, the finality of the Office Action mailed January 28, 2003 is premature and should be withdrawn.

The Amendments Should Have Been Reasonably Expected

Even accepting, *arguendo*, that the newly asserted obviousness rejection in view of the '371 patent was necessitated by Applicants' amendment, the Examiner should reasonably have expected such an amendment, making finality of the rejection improper. M.P.E.P. § 706.07(a). The Examiner, in the non-final Office Action mailed March 7, 2002, rejected claims 1, 5, and 9-12 under 35 U.S.C. § 102(b) in view of the '208 patent. In relevant part, the Examiner characterized the '208 patent disclosing pharmaceutical compositions of polyclonal antibodies that satisfied every limitation of the instant claims. As noted in Applicants' Reply of June 6, 2002, the '208 patent teaches pharmaceutical compositions containing antibodies that recognize tumor-specific antigens for the treatment of cancer. By contrast, Applicants' invention is used for the treatment of allergies and allergic reaction. Accordingly, claim 1 was amended to limit the types of antibodies encompassed by the claims to only those antibodies that react with or bind to proteins or epitopes derived from an inhaled, ingested, or airborne allergen. This amendment effectively removed the pharmaceutical compositions of the '208 patent from within the scope of Applicants' claims because the antibodies of the '208 patent recognize tumor-specific proteins or epitopes, not ones derived from inhaled, ingested, or airborne allergens.

The Examiner should have reasonably expected such a claim amendment. The present application is entitled "Polyclonal Antibody Composition for Treating Allergy" (emphasis added). And, in describing the allergic responses suitable for treatment using the methods and compositions of the invention, Applicants point out that "the allergens

enter the body of a patient through inhalation, ingestion, or through the skin" (Specification, page 3, lines 14-16). The specification, when read in its entirety, makes clear that Applicants invention is directed to the treatment of allergies. Accordingly, in view of the '208 patent, the Examiner should have reasonably expected Applicants to amend the claim 1 in a manner that excludes the treatment of cancer. For this reason alone, finality of the January 28, 2003 Office Action is premature and should be removed.

CONCLUSION

Applicants respectfully submit that the finality of new rejection asserted in the Office Action mailed January 28, 2003 was premature and should be removed. No fee is believed due in connection with this Petition. However, if there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: July 24, 2003

Kristina Bieker-Brady, Ph.D.
Reg. No. 39,109

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045

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Guy Beardsley
Printed name of person mailing correspondence

Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	John S. Haurum *et al.*	Art Unit:	1644
Serial No.:	09/866,573	Examiner:	Patrick J. Nolan
Filed:	May 25, 2001	Customer No.:	21559
Title:	POLYCLONAL ANTIBODY COMPOSITION FOR TREATING ALLERGY		

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PETITION FOR EXTENSION OF TIME

Pursuant to 37 C.F.R. § 1.136, applicant hereby petitions that the period for replying to the Final Office Action that was mailed in connection with the above-captioned application on January 28, 2003 be extended for three months, to and including July 28, 2003.

Enclosed is a check for $465.00 for the fee required by 37 C.F.R. § 1.17(a). If there are any other charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: July 24, 2003

Kristina Bieker-Brady, Ph.D.
Reg. No. 39,109

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045